K080380

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
SAS™ FluAlert A & B Test

This 510(k) summary of safety and effectiveness submission is in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted by:	SA Scientific, Ltd. 4919 Golden Quail San Antonio, TX 78240 210-699-8800
Establishment Reg. No:	1645225
Contact Person:	Robbi Perry
Date Prepared:	July 20, 2009
Proprietary Name:	SAS™ FluAlert A & B Test
Classification Name:	Antigens, CF (including CF control), Influenza virus A, B, C
Device Classification:	21 CFR Part 866.3330
Regulatory Class:	Class II
Classification Advisory Committee:	Microbiology
Product Code:	GNX
Substantial Equivalence:	Substantially equivalent to the SAS™ individual devices-SAS™ Influenza A Test (K044141) and SAS™ Influenza B Test (K041439), manufactured by SA Scientific, Ltd., San Antonio, TX.
Device Description:	The SAS™ FluAlert A & B Test utilizes antibodies against influenza type A and influenza type B viral nucleoproteins. After the extraction has been completed, the sample is placed into two separate sample wells. The specimen is absorbed and migrates via capillary action through membranes that contain dried gold conjugated antibody, which is specific for either influenza A or influenza B viral nucleoproteins. If these nucleoproteins are present, a "half-sandwich" immunocomplex is formed. The membrane contains immobilized antibody to influenza A or influenza B nucleoproteins, respectively, which bind the "half sandwich" complex. Thus, in the presence of influenza nucleoproteins, a "whole sandwich" immunocomplex is formed and a visible, pink-colored line develops in the specimen zone of the test device. In the absence of an influenza antigen, a "sandwich" immunocomplex is not formed and a negative result is indicated. To serve as a procedural control, a pink-colored control line will always appear in the control zone of each strip regardless of the presence or absence of influenza A or influenza B nucleoproteins.
Intended Use:	SAS™ FluAlertA&B Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. Negative results should be confirmed via culture. This test is not intended for

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the detection of Influenza Type C viral antigen. This test is for professional use only.

Negative results do not preclude infection with influenza A or B and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.

Conditions for Use: For prescription use only.

Quality Controls: The SAS™ Influenza A & Influenza B Test provides two (2) internal procedural quality controls. It is recommended that external quality controls be assayed following the user's laboratory's standard quality control procedures and in conformance with local, state and federal regulations or accreditation organizations as applicable

Device comparison: The SAS™ Influenza A & Influenza B tests are rapid immunoassay tests utilizing immunochromatographic technology for the visualization of Influenza A & Influenza B viral nucleoprotein antigens. Each utilizes an antibody conjugated to colored particles and an antibody printed onto a membrane. The chemistry of the predicate devices and the proposed device is identical; the only differnce is the plastic cassette.

Performance Summary: The SAS™ FluAlert A&B test performed substantially equivalent to the predicate devices, SAS™ Influenza A and SAS Influenza Flu B Tests mentioned above. This was verified by comparison to freshly collected nasal wash and nasal aspirate specimens.

Cross-reactivity and interference studies were performed on viral and bacterial strains commonly found in the human respiratory tract. None of the organisms interfered or cross-reacted with the performance of the SAS™ FluAlert A& B test.

Clinical Summary:

Prospective Clinical Study: The SAS™ FluAlert A&B Test combines the immunoassay test strips from the individual SAS™ Influenza A and SAS™ Influenza B Tests into one side-by-side plastic cassette. There are no other changes made to this test. In these studies, the users compared the combined test to the individual tests for evaluation of user interpretations. Please see: "Results Summary: SAS™ Influenza A and SAS™ Influenza B Individual Devices compared to cell culture or DFA" chart for comparison of the individual tests to cell culture/DFA.

Four clinical trial sites, in Texas and South Dakota, tested four hundred sixty one (461) nasal clinical specimens blindly and prospectively comparing the SAS™ Influenza A Test and The SAS™ FluAlert A&B (combined) Test performance. The SAS™ Influenza A Test and SAS™ FluAlert A&B Test had a positive percent agreement of 97.2% and a negative percent agreement of 99.7%. Thirteen samples yielded invalid results. These data were not included in the totals.

Four clinical trial sites, in Texas and South Dakota, tested four hundred sixty one (461) nasal clinical specimens blindly and prospectively comparing the SAS™ Influenza B Test and the SAS™ FluAlert A&B (combined) Test performance. The SAS™ Influenza B test and SAS™ FluAlert A&B Test had a positive percent agreement of 98.7% and a negative percent agreement of 99.7%.

Clinical sites collected the nasal wash samples from an approximately equal mix of adult (>21 years) and pediatric patients (0-21 years). The nasal aspirate samples were collected predominately from pediatric patients.

Fresh Prospective Nasal Aspirates:

	SAS Influenza A			Total
		+	-	
SAS A/B Combo	+	44	0	44
	-	1	137	138
Total		45	137	182
Positive % Agreement: 97.8% (95% CI 87-100%)				
Negative % Agreement: 100% (97% CI 95-100%)				

	SAS Influenza B			Total
		+	-	
SAS A/B Combo	+	37	0	37
	-	0	145	145
Total		37	145	182
Positive % Agreement: 100% (95% CI 97-100%)				
Negative % Agreement: 100% (95 % CI 88-100%)				

Fresh Prospective Nasal Washes:

	SAS Influenza A			Total
		+	-	
SAS A/B Combo	+	26	1	27
	-	1	251	252
Total		27	252	279
Positive % Agreement: 96.3% (95% CI 79-100%)				
Negative % Agreement: 99.6% (95%CI 97-100%)				

	SAS Influenza B			Total
		+	-	
SAS A/B Combo	+	40	1	41
	-	1	237	238
Total		41	238	279
Positive % Agreement: 97.6% (95% CI 86-100%)				
Negative % Agreement: 99.6% (95% CI 97-100%)				

Results Summary: Fresh Nasal Washes and Aspirates:

	SAS Influenza A			Total
		+	-	
SAS A/B Combo	+	70	1	71
	-	2	388	390
Total		72	389	461
Positive % Agreement: 97.2% (95% CI 89-100%)				
Negative % Agreement: 99.7% (95% CI 98-100%)				

	SAS Influenza B			Total
		+	-	
SAS A/B Combo	+	77	1	78
	-	1	382	383
Total		78	383	461
Positive % Agreement: 98.7% (95% CI 92-100%)				
Negative % Agreement: 99.7% (95% CI 98-100%)				

Note: Performance characteristics for detecting the 2009 H1N1 influenza virus from human specimens have not been established

Demographics of Fresh Samples:

Age (years)	Number of Nasal Wash specimens	% of Total NW Specimens	Number of Nasal Aspirate Specimens	% of Total NA Specimens
0-5	16	5.7%	73	40.1%
6-21	21	7.5%	108	59.3%
22 - 65	25	9.0%	1	0.6%
>65	9	3.2%	0	
Not Determined	208	74.5%	0	
Total	279		182	

Retrospective Study:

To supplement the prospective study, 191 frozen, archived, nasal wash samples from a children's hospital in Texas were blindly assayed comparing the individual SAS™ Influenza A Test and the individual SAS™ Inflluenza B Test to the SAS™ FluAlert A&B (combined) Test. For these samples, the positive percent agreement with the Influenza A Test is 100% and negative percent agreement is 99.3%, while positive percent agreement with the Influenza B Test was 94.7% and negative percent agreement is 98.0%

		SAS™ Influenza A Test +	-	
SAS™ Flu Alert A&B Combined Test	+	27	1	28
	-	0	163	163
Total		27	164	191

Positive % Agreement: 100% (95% CI 84-100%)
Negative % Agreement: 99.3% (95% CI 96-100%)

		SAS™ Influenza B Test +	-	
SAS™ FluAlert A & B Combined Test	+	36	3	39
	-	2	150	152
Total		38	153	191

Positive % Agreement: 94.7% (95% CI 81-99%)
Negative % Agreement: 98.0% (95% CI 94-99%)

Reproducibility:

The reproducibility of the SAS™ FluAlert A&B Test was evaluated at three clinical sites. Three or four non-professional users per site tested the SAS™ FluAlert A&B Test against a panel of approximately 30 aliquots each of six (6) panel members over a two-week period. Specimens were comprised of pooled nasal aspirates and included two (2) levels of positives for influenza A and two (2) for influenza B and two (2) negatives. The low and medium positives for influenza A contained H3N2 A/Hong Kong/8/68 and the low and medium positives for influenza B contained B/Allen/45. Negative specimens for influenza A contained H3N2 A/Hong Kong/8/68 and negative specimens for influenza B contained B/Allen/45, but both were in concentrations below the

limit of detection. Although 30 aliquots of each were prepared, in some cases the total number was fewer than 30 because of spillage or pipetting errors.

	Panel Member	Influenza A High Negative	Influenza A Low Positive	Influenza A Moderate Positive	Influenza B High Negative	Influenza B Low Positive	Influenza B Moderate Positive
	Viral Titer Final Concentration $TCID^{50}$/0.2 ml.	1.8×10^3	7×10^3	1.4×10^4	2.8×10^2	1.1×10^3	2.2×10^3
Agreement with Expected Result	Site 1	29 Neg/30 96.7%	26 Pos/30 86.6%	29 Pos/30 96.7%	28 Neg/29 96.6%	29 Pos/30 96.7%	29 Pos/29 100%
	Site 2	29 Neg/30 96.7%	26 Pos/29 89.7%	29 Pos/29 100%	30 Neg/30 100%	29 Pos/30 96.7%	30 Pos/30 100%
	Site 3	28 Neg/30 93.3%	27 Pos/30 90.0%	30 Pos/30 100%	26 Neg/29 89.7%	29 Pos/30 96.7%	30 Pos/30 100%
	Total Agreement	95.6%	88.8%	98.9%	95.4%	96.7%	100%

Analytical Sensitivity (Limit of Detection):

The limit of detection (LOD) for the SAS™ FluAlert A&B Test was determined for five (5) each influenza A and Influenza B viral strains. Each strain was received from ATCC with a known $TCID_{50}$ concentration. Each strain was serially diluted in SAS™ FluAlert extraction buffer. Strains were assayed in triplicate using the SAS™ FluAlert A&B Test until no positive signal could be seen. Results are summarized below.

Influenza Viral Strain	**ATCC**	**LoD** $TCID_{50}$/0.2 ml
H1N1 A/PR/3/34	VR-95	1.2×10^5
H3N2 A/Aichi/2/68	VR-547	5.6×10^2
H3N2 A/Hong Kong/8/6/8	VR-544	3.5×10^3
H1N1 A/FM/147	VR-97	7.9×10^3
H3N2 A/Victoria/3/75	VR-822	4.5×10^5
Influenza B B/Lee/40	VR-101	9.9×10^4
Influenza B B/Allen/45	VR-102	5.6×10^2
Influenza B B/Mass/3/66	VR-523	4.5×10^2
Influenza B B/Taiwan/2/62	VR-295	3.5×10^1
Influenza B B/Maryland/1/59	VR-296	1.6×10^2

Cross Reactivity Study: Twenty-two virus strains were obtained from ATCC or other commercial sources. Each cultured viral strain was tested on the SAS™ FluAlert A&B Test in these concentrations. The results are summarized below.

Virus	ATTC/Lot #	Concentration	"A" portion of the SAS™ FluAlert A&B	"B" portion of the SAS™ FluAlert A&B
Adenovirus 5	10-198-000	1.2×10^{10}	Neg	Neg
Adenovirus 7	VR7	3.2×10^{3} $TCID_{50}$ /0.2 ml	Neg	Neg
Adenovirus 10	VR1087	3.2×10^{3} $TCID_{50}$ /0.2 ml	Neg	Neg
CoxsackieA9	VR186	3.2×10^{2} $TCID_{50}$ /0.2 ml	Neg	Neg
CoxsackieB5	VR185	3.2×10^{6} $TCID_{50}$ /0.2 ml	Neg	Neg
Cytomegalovirus	021301	20 µg/ml	Neg	Neg
Echovirus11	VR1052	NA	Neg	Neg
Echovirus3	VR1040	1×10^{4} $TCID_{50}$ /0.2 ml	Neg	Neg
Echovirus 6	VR1044	3.2×10^{6} $TCID_{50}$ /0.2 ml	Neg	Neg
HSV-1	2J30000	15 µg/ml	Neg	Neg
HSV-2	8J29502	15 µg/ml	Neg	Neg
Varicella zoster	1102097	12 µg/ml	Neg	Neg
Parainfluenza 1	VR907	5.6×10^{6} $TCID_{50}$ /0.2 ml	Neg	Neg
Parainfluenza 2	VR92	1.8×10^{5} $TCID_{50}$ /0.2 ml	Neg	Neg
Parainfluenza 3	VR93	3.2×10^{6} $TCID_{50}$ /0.2 ml	Neg	Neg
RSV Long	VR26	$0.1 \times 10^{5.5}$ $TCID_{50}$ /0.2 ml	Neg	Neg
RSV B	VR1400	$0.1 \times 10^{5.25}$ $TCID_{50}$ /0.2 ml	Neg	Neg
Influenza B Allen	VR102	3.2×10^{3} $TCID_{50}$ /0.2 ml	Neg	
Influenza B Lee	VR101	3.2×10^{6} $TCID_{50}$ /0.2 ml	Neg	
Influenza B Mass	VR523	1.8×10^{3} $TCID_{50}$ /0.2 ml	Neg	
Influenza B Maryland	VR296	1×10^{4} $TCID_{50}$ /0.2 ml	Neg	
Influenza B Taiwan	VR295	5.6×10^{2} $TCID_{50}$ /0.2 ml	Neg	
Influenza A (H1N1) PR	VR95	1.8×10^{4} $TCID_{50}$ /0.2 ml		Neg
Influenza A (H3N2) Aichci	VR547	1.8×10^{6} $TCID_{50}$ /0.2 ml		Neg
Influenza A (H3N2) Hong Kong	VR544	5.6×10^{4} $TCID_{50}$ /0.2 ml		Neg
Influenza A FM	VR97	3.2×10^{4} $TCID_{50}$ /0.2 ml		Neg
Influenza A (H3N2) Victoria	VR822	1.8×10^{6} $TCID_{50}$ /0.2 ml		Neg

One yeast and fourteen bacterial strains were obtained from ATCC or other commercial sources. Each cultured bacterial or yeast strain was diluted to a concentration of 1×10^{8} cfu/ml and tested on the SAS™ FluAlert A&B Test. The results are summarized below.

Bacteria or Yeast	"A" portion of the SAS™ FluAlert A&B	"B" portion of the SAS™ FluAlert A&B
Candida albicans	Neg	Neg
Chlamydia trachomatis	Neg	Neg
Corynebacterium diphtheriae	Neg	Neg
Haemophilus influenza	Neg	Neg

Klebsiella pneumoniae	Neg	Neg
Serratia marcescens	Neg	Neg
Staphylococcus epidermidis	Neg	Neg
Staphylococcus aureus	Neg	Neg
Streptococcus sp gr A	Neg	Neg
Streptococcus sp gr F	Neg	Neg
Streptococcus sp gr G	Neg	Neg
Streptococcus pneumoniae	Neg	Neg
Mycoplasma pneumoniae	Neg	Neg
Neisseria meningitidis	Neg	Neg
Pseudomonas aeruginosa	Neg	Neg

Interference Study:

The analytical specificity of the A portion of the SAS™ FluAlert A&B was evaluated by testing a panel of 22 viruses, 14 bacteria, and one yeast species which may be found in the respiratory tract. For the A portion of the test, Influenza Whole Virus Strain A/FM/147 (ATCC VR97) at a titer of 7.9×10^3 $TCID_{50}$/0.2 ml. was added to viral cultures and viral antigens at the concentrations in the table below and bacterial and yeast cultures at concentrations of 1×10^8 cfu/ml. For the B portion of the test, Influenza Whole Virus Strain B/Mass/3/66 (ATCC VR523) at a titer of 3.2×10^3 $TCID_{50}$/0.2 ml. was added to viral cultures in the concentrations in the table below and bacterial and yeast cultures at 1×10^8 cfu/ml.

Results are summarized below:

Virus	ATTC/Lot #	Concentration	"A" Portion of the SAS™ FluAlert A&B	"B" Portion of the SAS™ FluAlert A&B
Adenovirus 5	10-198-000	1.2×10^{10} $TCID_{50}$ /0.2 ml	Pos	Pos
Adenovirus 7	VR7	3.2×10^3 $TCID_{50}$ /0.2 ml	Pos	Pos
Adenovirus 10	VR1087	3.2×10^3 $TCID_{50}$ /0.2 ml	Pos	Pos
CoxsackieA9	VR186	3.2×10^2 $TCID_{50}$ /0.2 ml	Pos	Pos
CoxsackieB5	VR185	3.2×10^6 $TCID_{50}$ /0.2 ml	Pos	Pos
Cytomegalovirus	021301	20 µg/ml	Pos	Pos
Echovirus11	VR1052	NA	Pos	Pos
Echovirus3	VR1040	1×10^4 $TCID_{50}$ /0.2 ml	Pos	Pos
Echovirus6	VR1044	3.2×10^6 $TCID_{50}$ /0.2 ml	Pos	Pos
HSV-1	2J30000	15 µg/ml	Pos	Pos
HSV-2	8J29502	15 µg/ml	Pos	Pos
Varicella zoster	1102097	12 µg/ml	Pos	Pos
Parainfluenza 1	VR907	5.6×10^6 $TCID_{50}$ /0.2 ml	Pos	Pos
Parainfluenza 2	VR92	1.8×10^5 $TCID_{50}$ /0.2 ml	Pos	Pos
Parainfluenza 3	VR93	3.2×10^6 $TCID_{50}$ /0.2 ml	Pos	Pos
RSV Long	VR26	$0.1 \times 10^{5.5}$ $TCID_{50}$ /0.2 ml	Pos	Pos
RSV B	VR1400	$0.1 \times 10^{5.25}$ $TCID_{50}$ /0.2 ml	Pos	Pos
Influenza B Allen	VR102	3.2×10^3 $TCID_{50}$ /0.2 ml	Pos	
Influenza B Lee	VR101	3.2×10^6 $TCID_{50}$ /0.2 ml	Pos	
Influenza B Mass	VR523	1.8×10^3 $TCID_{50}$ /0.2 ml	Pos	
Influenza B Maryland	VR296	1×10^4 $TCID_{50}$ /0.2 ml	Pos	
Influenza B Taiwan	VR295	5.6×10^2 $TCID_{50}$ /0.2 ml	Pos	
Influenza A (H1N1) PR	VR95	1.8×10^4 $TCID_{50}$ /0.2 ml		Pos

Influenza A (H3N2) Aichci	VR547	1.8×10^6 $TCID_{50}$ /0.2 ml		Pos
Influenza A (H3N2) Hong Kong	VR544	5.6×10^4 $TCID_{50}$ /0.2 ml		Pos
Influenza A FM	VR97	3.2×10^4 $TCID_{50}$ /0.2 ml		Pos
Influenza A (H3N2) Victoria	VR822	1.8×10^6 $TCID_{50}$ /0.2 ml		Pos

One yeast and fourteen bacterial strains were obtained from ATCC or other commercial sources. Each cultured bacterial or yeast strain was diluted to a concentration of 1×10^8 cfu/ml and tested on the SAS™ FluAlert A&B Test. The results are summarized below.

Bacteria or Yeast	**"A" portion of the SAS™ FluAlert A&B**	**"B" portion of the SAS™ FluAlert A&B**
Candida albicans	Pos	Pos
Chlamydia trachomatis	Pos	Pos
Corynebacterium diphtheriae	Pos	Pos
Haemophilus influenza	Pos	Pos
Klebsiella pneumoniae	Pos	Pos
Serratia marcescens	Pos	Pos
Staphylococcus epidermidis	Pos	Pos
Staphylococcus aureus	Pos	Pos
Streptococcus sp gr A	Pos	Pos
Streptococcus sp gr F	Pos	Pos
Streptococcus sp gr G	Pos	Pos
Streptococcus pneumoniae	Pos	Pos
Mycoplasma pneumoniae	Pos	Pos
Neisseria meningitidis	Pos	Pos
Pseudomonas aeruginosa	Pos	Pos

Expected Values:

Influenza prevalence varies year to year, with the highest number of cases in the fall and winter months in the US. During the period of September 30, 2007 to April 5, 2008, prevalence in the US for both influenza A and influenza B was 18.5%, with 74% of those cases attributed to influenza A and 26% attributed to influenza B. For studies conducted on the SAS™ FluAlert A&B Test, during the 2007-2008 and 2008-2009 seasons, prevalence for fresh, prospective nasal washes and nasal aspirates was 15.1% for influenza A and 16.5% for influenza B.

Conclusion of Performance Data:

The performance agreement of all clinical samples for the predicate devices and the proposed new device, FluAlert A&B, is 98% for the positive samples for influenza A, and >99% for negative samples, and is > 97% for the positive samples for influenza B is and >99% for negative samples, indicating that the new device is substantially equivalent to the predicate devices

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Regulatory Affairs
SA Scientific, Ltd.
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San Antonio, TX 78240

Re: K080380
Trade/Device Name: SAS™ FluAlert A&B
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: Class II
Product Code: GNX
Dated: June 2, 2009
Received: June 4, 2009

Dear Ms. Perry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K080380

Device Name: SAS™ FluAlert A & B Test

Indication For Use:

SAS™ FluAlert A & B Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of Influenza A and Influenza B viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of Influenza Type C viral antigen. This test is for professional use only.

Negative results do not preclude infection with influenza A or influenza B and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.

Prescription Use __X____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Uwe Scherf

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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